IN THE UNITED STATES PATENT AND TRADEMARK OFFICE In re Patent Application of Atty Dkt. 117-473 C# M# O だTC/A.U. ARTHUR, M. et al. MAR 2 9 2005 Serial No. 10/650,074 Examiner: Filed: August 28, 2003 Date: March 29, 2005 TREATMENT FOR LIVER DISEASE Title: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir: **INFORMATION DISCLOSURE STATEMENT** This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon. Correspondence Address Indication Form Attached. Fees are attached as calculated below: Total effective claims after amendment minus highest number previously paid for (at least 20) = 20 \$0.00 (1202)/\$0.00 (2202) \$ x \$50.00 Independent claims after amendment minus highest number previously paid for (at least 3) =x \$200.00 \$0.00 (1201)/\$0.00 (2201) \$ If proper multiple dependent claims now added for first time, (ignore improper); add \$360.00 (1051)/\$180.00 (2051) \$ Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) One Month Extension \$120.00 (1251)/\$60.00 (2251) Two Month Extensions \$450.00 (1252)/\$225.00 (2252) Three Month Extensions \$1020.00 (1253/\$510.00 (2253) Four Month Extensions \$1590.00 (1254/\$795.00 (2254) \$ Terminal disclaimer enclosed, add \$130.00 (1814)/ \$65.00 (2814) \$ Applicant claims "small entity" status. Statement filed herewith Rule 56 Information Disclosure Statement Filing Fee \$180.00 (1806) Assignment Recording Fee \$40.00 (8021) Other: TOTAL FEE ENCLOSED \$ 0.00 The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A <u>duplicate</u> copy of this sheet is attached. 1100 North Glebe Road, 8th Floor NIXON & VANDERHYE P.C.

By Atty: Mary J. Wilson, Reg. No. 32,955

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Patent Application of	0 2005	Confirmation No. 7212		
ARTHUR, M. et al.	MAR 2 9 2005 BY	Atty. Ref.: 117-473		
Serial No. 10/650,074	PIENT & TRADE	Group:		
Filed: August 28, 2003		Examiner:		
For: TREATMENT FOR	LIVER DISEASE			
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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450)	March 29, 2005		

Sir:

INFORMATION DISCLOSURE STATEMENT

1.	PTO-1449 Pursuant to 37 CFR 1.97(b) [within 3 months of filing or prior to 1st Office Action on	the merits
2.(a)	Statement Pursuant to 37 CFR 1.97(c) [before Final Office Action or Allowance (requires Rule Statement or Rule 17(p) fee)]	97(e) N/C
2 .(b)	Fee Payment Pursuant to 37 CFR 1.97(c) [before Final Office Action or Allowance (requires Rule Statement or Rule 17(p) fee)]	97(e) \$180.00
3.	Pursuant to 37 CFR 1.97(d) [after Final Office Action or Allowance (requires Rule 97 Statement and Rule 17(p) fee), but before final fee payr	` '

The following are submitted in the above-identified application in compliance with 37 C.F.R. §§ 1.97 and 1.98:

4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith.

ARTHUR, M. et al. Serial No. 10/650,074 March 29, 2005

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This paper is submitted in accordance with:

\boxtimes	5.	37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]					
	6.	37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier] and					
		The required Statement made in item 8 below; or					
		The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.					
	7.	37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and					
		The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and					
		b) The required Statement is stated in item 8 below.					
	8.	Statement under 37 CFR 1.97(e)					
		The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no mothan three months prior to the filing of this IDS); or	:h า				
		No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterprofession application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.	par 37				
	9.	Please charge all deficiency fees associated with the submission of this nformation Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy othis document are enclosed.	of				

ARTHUR, M. et al. Serial No. 10/650,074 March 29, 2005

Respectfully submitted, NIXON & VANDERHYE P.C.

By:

Mary J Wilson

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Sheet 1	of 2	DE ATTY. DO	CKET NO	SERIAL NO.			
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			PATENT DOCUMENTS	***			
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INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	IF APPROPRIATE	
	6,197,749	3/2001	Hamuro et al				
	2002/0037934	3/2002	Amin et al				
	6,107,273	8/2000	Jameson et al			<u></u>	
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		FOREI	GN PATENT DOCUMENT	S	L		-
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	WO 91/13622	9/1991	WIPO			•	
	WO 93/12789	7/1993	WIPO				
	WO 97/32585	9/1997	WIPO				
•	WO 02/18330	3/2002	WIPO				
	OTHER DOCUM	ENTS (incl	uding Author, Title, Date,	Pertinent pa	iges, etc.)	
		<u>`</u>	ynamic Effects of Ketanserin in				le of
			Hypertension", Hepatology 7(4)				_
		ypertension: S	erotonin and Pathogenesis", Ca	rdiovascular Dru	igs and The	rapy 4:3	33-35
	(1990)						
			d Treatment of Portal Hypertens		erin and Prop	pranolol	in
			tic Rats", Hepatology 15:878-88 Apoptosis of Rat and Human He		olle A Moo	honiem	for
	_		solution of Liver Fibrosis", Hepa	•			
	Abstract No. 671 – X		columnia Elvoi i ibiosis, i icpe		,, (2001) -	/-V-\ULU	
	Wright et al, "Gliotoxi	n Stimulates th	ne Apoptosis of Human and Rat		nd Enhance	s the	
	- 		', Gastroenterology 121(3):685-6				
			Development of Fibrosis and Cir		acetamide R	at Mode	el",
	Hepatology 34(4):516	6A (2001) – AA	ASLD Abstract No. 1377 – XP00	9022978			

Alcolado et al, "Pathogenesis of liver fibrosis", Clinical Science 92:103-112 (1997)

*Examiner Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include

P/C04/011) – Abstract, XP009022977

copy of this form with next communication to application.

Digestive Diseases and Sciences 48(8):1642-1647 (2003)

Hepatology 36(4):486A (2002) – Abstract, XP009030944

of Pharmaceology 88:104P (2002) - Abstract, XP009030945

Wright et al, "Gliotoxin stimulates apoptosis in cultured rat hepatic stellate cells", 30:98 (1999) (EASL Abstract

Matsui et al, "Protective effect of sulfasalazine on hepatic ischemia-reperfusin injury in rats", Japanese Journal

Dekel et al, "Gliotoxin Ameliorates Development of Fibrosis and Cirrhosis in a Thioacetamide Rat Model",

Oakley et al, "Sulfasalazine Inhibits NFKB Activity and Induces Apoptosis of Rat Hepatic Stellate Cells",

Form PTO-FB-A820 (Also PTO-1449)

INFORM	MATION DISCLOSUR	E ATTY. DO	OCKET NO.	SEF	RIAL NO.	, 4 n			
CITATION			117-473 10/650,074						
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<u> </u>	OTHER DOCUME	NTS (inc	luding Autho	r, Title, Date, Per	tinent p	ages, etc.	.)		
	Elsharkawy et al, "Persi	istent Activa	ation of Nuclear	Factor- <i>k</i> B in Cultured	Rat Hepat	tic Stellate C	Cells Involves		
	the Induction of Potentia	•		and Prolonged Chan	ges in the E	Expression of	of I <i>κ</i> B Family		
	Proteins", Hepatology 3 Friedman, Scott L., "The			ibrosis" The New Fi	ngland Jou	rnal of Medi	cine 328·1828-		
	1835 (1993)			ibroolo , Tho How El	igiana ooa	irrial of Wica	0110 020.1020		
	Friedman, Scott L., "Mo		-	. —	ated Cellula	ar Response	to Tissue		
	Injury", The Journal of E				IA in Norm	ad and Eibre	otio Dot Livor		
	Milani et al, "In Situ Hyb Evidence for Predomina								
	Trim et al, "Hepatic Stel	late Cells E	xpress the Low	Affinity Nerve Growth	Factor Re	eceptor p75	and Undergo		
	Apoptosis in Response	to Nerve G	rowth Factor Stir	mulation", American .	Journal of F	Pathology 1	56(4):1235-124:		
	(2000)	ms of Spor	staneous Resolut	tion of Pat Liver Fibro	eie" I Clir	n Invest 10	12(3):538 540		
lredale et al, "Mechanisms of Spontaneous Resolution of Rat Liver Fibrosis", J. Clin. Invest. 102 (1998)						2(3).330-349			
		Calès, P., "Apoptosis and liver fibrosis: antifibrotic strategies", Biomed. & Pharmacother. 52:259-263 (1998)							
. 8	Fischer et al, "Expression Stellete Colle", Contract			•	or and Apo	optosis Indu	ction in Hepatic		
-	Stellate Cells", Gastroei Gressner, Axel M., "The		<u> </u>		e Injury: Ar	nontosis Res	stores Cellular		
	Homeostasis", Gastroer	•	_		o irijai y. Aş	optosis rtc.	stores octional		
	Gong et al, "Transformation-dependent Susceptibility of Rat Hepatic Stellate Cells to Apoptosis Induced						Induced by		
Soluble Fas Ligand", Hepatology 28(2):492-502 (1998)						Liver Disease			
Iredale, John P., "Hepatic Stellate Cell Behavior during Resolution of Liver Injury", Seminars in Liver Di 21(3):427-436 (2001)						Liver Disease			
Issa et al, "Apoptosis of hepatic stellate cells: involvement in resolution of biliary fibrosis and regula soluble growth factors", Gut 48(4):548-557 (2001)						gulation by			
lwamoto et al, "Induction of apoptosis in rat hepatic stellate cells by disruption of integrin-mediated adhesion", J. Lab. Clin. Med. 134(1):83-89 (1999) Lang et al, "Nuclear factor κB in proliferation, activation, and apoptosis in rat hepatic stellate cells",							ated cell		
							ells", Journal of		
	Hepatology 33(1):49-58	(2000)				-			
Murphy et al, "Inhibition of Apoptosis of Activated Hepatic Stellate Cells by Tissue Inhibitor of Metalloproteinase-1 Is Mediated via Effects on Matrix Metalloproteinase Inhibition", The Journal of B							ol of Diological		
	Chemistry 277(13):1106			ix ivietalioproteiriase	irifibilion ,	ine Journa	ii oi biologicai		
	Saile et al, "CD95/CD95			e Hepatic Stellate Ce	II", Americ	an Journal o	of Pathology		
151(5):1265-1272 (1997)									
Saile et al, "Transforming Growth Factor β and Tumor Necrosis Factor α Inhibit Both Apoptosis Proliferation of Activated Rat Hepatic Stellate Cells", Hepatology 30(1):196-202 (1999)						and			
	Wright et al, "Gliotoxin S						tro".		
	International Cells of the			•			· ·		
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